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Attn: Mr Matthew Forward

Dear Sirs

MERLIN MD PTE LTD
PCT INTERNATIONAL APPLICATION NO. PCT/SG2004/000319
"IMPLANTABLE MEDICAL DEVICES WITH GOOD VISIBILITY AND MECHANICAL PROPERTIES"

We refer to the Written Opinion dated 12 May 2005.

The examiner asserts that claims 1 to 3 and 19 to 23 are not novel and all claims are not inventive when compared to US 2003/0093111, EP 0947204 and US 6,024,765.

We are surprised at the Written Opinion since previous claim 9 was considered novel in the International Preliminary Report on Patentability (IPRP Chapter I) against the same prior art documents.

We submit an amended set of claims to overcome the examiner's objection. Specifically, claims 4, 6, 8 and 10 have been incorporated into claim 1.

Also, we submit that none of the cited document discloses a stent made from an alloy selected from the group of platinum alloy in the specific % composition for any of the platinum alloys defined in claim 1 of the present invention.

US 2003/0093111 [Ken] merely discloses an alloy of "platinum, stainless steel, nickel-titanium alloy, tungsten, gold, rhenium, palladium, rhodium, ruthenium, titanium, nickel" at page 2 paragraph 24. Ken does not disclose iridium, let alone in any specific % composition. Ken does not disclose a specific % composition of platinum:tungsten alloy, platinum:rhodium alloy, platinum:ruthenium alloy or platinum:nickel alloy.

EP 0947204 [Cordis] discloses that "the first material is preferably selected from the group consisting of gold, platinum, tantalum, iridium, tungsten, alloys thereof and any combination thereof" at page 7 paragraph 41. However, Cordis does not disclose a platinum:iridium alloy with a composition of 70-80% of platinum and 20-30% iridium. Cordis does not disclose a specific % composition of platinum:iridium alloy or platinum:tungsten alloy.

US 6,024,765 [Wallace] merely discloses that "suitable metals and alloys for the wire making up the device (100) include the Platinum Group metals, especially platinum, rhodium, palladium, rhenium, and other bio-compatible metals such as tungsten, gold, silver, tantalum, and alloys of these metals" at column 4 line 24. However, Wallace does not disclose iridium, let alone in any specific % composition. Wallace does not disclose a specific % composition of platinum:rhodium alloy or platinum:tungsten alloy.

The selection of the specific platinum alloys defined by the present invention advantageously provides an ultimate tensile strength to the stent greater than if it were made from stainless steel and other prior-art materials/alloys. This is not suggested or taught by the prior art. The ultimate tensile strength comparison is illustrated at Table 1 on page 11 of the description. Consequently, this enables the wall thickness of the stent to be reduced. Advantageously, a reduced wall thickness allows stents with a low profile to be deployed which improves manoeuvrability. Notwithstanding the excellent mechanical properties, the selection enables enhanced visibility and biocompatibility of the stent that are highly desired for intracranial deployment uses. Therefore the present invention produces an unexpected and unobvious result due to the selection of % of the platinum alloy components defined in claim 1. None of the cited documents even remotely set out to achieve the desirable outcomes of required strength, low profile and manoeuvrability. Hence, the claims of the present invention are now clearly distinguishable from the cited documents.

We look forward to receiving a favourable Written Opinion in due course.

Yours faithfully,

James Wan
Australian Patent Attorney
ALBAN TAY MAHTANI & DE SILVA

Encl. (with mail confirmation copy)

10/578806

 IAP20 Rec'd PCT/PTO 08 MAY 2006

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,

wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium;

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten;

wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium;

wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and

wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.

3. The stent according to claim 1, wherein the stent is a self-expandable stent.

4. The stent according to claim 1, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.

5. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.

6. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

7. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

8. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

9. The stent according to any one of claims 1 to 8, wherein the stent has a sidewall thickness of less than 0.0035".

10. The stent according to any one of claim 1 to 9, wherein the surface of the stent is modified by passive coatings.

11. The stent according to claim 10, wherein the coating is iridium oxide or titanium nitrate.

12. The stent according to claim 10, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

13. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

14. The stent according to claim 13, wherein the markers include end markers or center markers.

15. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; and

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams.

16. The device according to claim 15, wherein the welding is laser welding.

17. A delivery system for inserting a device an implantable medical device according to claim 1, within a bodily vessel, wherein the device is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the device, wherein the expandable medical device is mounted onto the balloon of the delivery catheter.

18. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the device is self-expandable, the delivery system comprising a delivery catheter and the device, wherein the device is mounted onto a distal portion of the delivery catheter.

19. The device according to claim 15, wherein the device is deployed at a pressure equal to or below 4atm.

20. The device according to claim 15, wherein the structure of the device provides a normalized radial force 18 to 19 grams per mm of length.

21. The device according to claim 20, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.

22. The device according to claim 15, wherein the device has a profile in a compressed delivery form of 0.020 inches.

23. The device according to claim 15, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.

24. The device according to claim 15, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

25. The device according to claim 15, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

26. The device according to claim 15, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

27. The device according to claim 15, wherein the device has a surface to length ratio between 1.1 to 1.3mm^2/mm to provide minimal vessel injury score.

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,

wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium;

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten;

wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium;

wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and

wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.

3. The stent according to claim 1, wherein the stent is a self-expandable stent.

~~4. The stent according to any one of claims 1 to 3, wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.~~

~~5~~4. The stent according to claim ~~4~~1, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.

~~6. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium.~~

~~7~~5. The stent according to claim ~~6~~1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.

~~8. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium.~~

~~9~~6. The stent according to claim ~~8~~1, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

~~10. The stent according to claim 1, wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.~~

~~11~~7. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

~~12~~8. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

~~13~~9. The stent according to any one of claims 1 to ~~12~~8, wherein the stent has a sidewall thickness of less than 0.0035".

~~14~~10. The stent according to any one of claim 1 to ~~13~~9, wherein the surface of the stent is modified by passive coatings.

~~15~~11. The stent according to claim ~~14~~10, wherein the coating is iridium oxide or titanium nitrate.

~~16~~12. The stent according to claim ~~14~~10, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

~~17~~13. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

~~18~~14. The stent according to claim ~~17~~13, wherein the markers include end markers or center markers.

~~19~~15. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; and

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams.

~~20~~16. The device according to claim ~~19~~15, wherein the welding is laser welding.

~~21~~17. A delivery system for inserting a device an implantable medical device according to claim 1, within a bodily vessel, wherein the device is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the device, wherein the expandable medical device is mounted onto the balloon of the delivery catheter.

~~22~~18. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the device is self-expandable, the delivery system comprising a delivery catheter and the device, wherein the device is mounted onto a distal portion of the delivery catheter.

~~23~~19. The device according to claim ~~19~~15, wherein the device is deployed at a pressure equal to or below 4atm.

~~24~~20. The device according to claim ~~19~~15, wherein the structure of the device provides a normalized radial force 18 to 19 grams per mm of length.

~~25~~21. The device according to claim ~~24~~20, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.

~~26~~22. The device according to claim ~~19~~15, wherein the device has a profile in a compressed delivery form of 0.020 inches.

~~27~~23. The device according to claim ~~19~~15, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.

~~28~~24. The device according to claim ~~19~~15, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

~~29~~25. The device according to claim ~~18~~15, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

~~30~~26. The device according to claim ~~19~~15, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

~~31~~27. The device according to claim ~~19~~15, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.